UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,176	06/09/2005	Chikamasa Yama	04676.0184-00000	1747

22852 7590 04/09/2007

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER	
ALI, SHUMAYA B	
ART UNIT	PAPER NUMBER
3771	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/538,176	YAMA ET AL.	
	Examiner	Art Unit	
	Shumaya B. Ali	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 June 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/9/05,10/11/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Sladek US 6,039,042.

As to claim 10, Sladek discloses an inhalation device in figures 1-6 comprising: a main body formed cylindrically (12); a mouthpiece (11) provided at one end of the main body; a vessel (see canister of 40 in figs.1 and 2A) provided at the other end of the main body, the vessel being for containing a pharmaceutical composition which is pulverized into fine particles by an air-generated impact for dispersal in air (col.3, lines 45-50); an inhalation flow path (31) formed of the inner side space of the main body, the mouth piece and the vessel, the inhalation flow path being for flowing outside air containing the fine particles of the pharmaceutical composition from the vessel-side toward the mouthpiece-side (see fig.2A); an air inlet port (see "air flow path" in the labeled fig. 2A, attached below)for introducing the outside air to the inhalation flow path; and a divider (20B) for dividing the inhalation flow path, the divider having an orifice (an orifice is covered by 20B, see figs. 2B, 2C) for reducing the diameter of the inhalation flow path and being located downstream of the air inlet port. Sladek however lacks the explicit teachings of wherein the inhalation flow path has such a capacity that an air-generated impact can be applied to the pharmaceutical composition by the outside air, which is fed from the air inlet port

into the inhalation flow path located upstream of the divider by an air inhalation of user. However, it should be noted that the "air-generated impact" is provided by the air flow port/paths as claimed, and such air flow port/paths are taught by Sladek, thus, Sladek's device is inherently capable of providing air-generated impact and pulverization of the pharmaceutical composition.

As to claim 11, Sladek discloses the inhalation device according to claim 10 comprising: an air outlet (a path through apertures formed by ribs 29, see fig.1) which opens into the inhalation flow path; and an auxiliary flow path (20A) for feeding the outside air into the inhalation flow path through the air outlet by the air inhalation of user. Sladek further teaches the location of the orifice and the air outlet is such that the outside air flowing in from the air outlet is inhaled into the mouth of the user without passing through the orifice (see figs. 2A and 6).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Sladek US 6,039,042.

As to claim 1, Sladek in figures 1-8 discloses an inhalation device for transpulmonary administration a chamber (space inside the apparatus depicted in fig.2A, see labeled fig.2A attached below) for containing a pharmaceutical composition which is pulverized into fine particles by an air-generated impact for dispersal in air; an air inlet flow path (see labeled fig.2A, attached below) for introducing to the chamber outside air to apply the air-generated impact to the pharmaceutical composition and for injecting the outside air toward the pharmaceutical composition; an inhalation flow path (31) having a suction port (a path through apertures formed by ribs 29, see fig.1) located inside the chamber to inhale the pulverized pharmaceutical composition; a housing (body of the apparatus depicted in fig.2A, see labeled fig.2A attached below) for accommodating the chamber, the air inlet flow path, and the inhalation flow path; a mouthpiece (11) provided at one end of the housing, the mouthpiece being provided with a mouth-side flow path (11D) which communicates with the inhalation flow path, and an auxiliary

flow path (20A) for directly inhaling the outside air which does not communicate with the inhalation flow path and the mouth-side flow path. Sladek, however, lacks explicit teachings of wherein the inhalation device for transpulmonary administration is configured such that the air-generated impact is applied to the pharmaceutical composition by the outside air which flows into the chamber by inhalation-induced pressure generated when a user (patient) inhales air, and the pulverized pharmaceutical composition is introduced to the mouth-side flow path, and at the same time the outside air is directly introduced to the auxiliary flow path by the inhalation-induced pressure. However, it should be noted that the "air-generated impact" and "pulverized pharmaceutical composition" are provided by the air flow port/paths as claimed, and such air flow port/paths are taught by Sladek, thus, Sladek's device is inherently capable of providing air-generated impact and pulverization of the pharmaceutical composition. Therefore, it would have been obvious to one of ordinary skill in the art to consider the use of Sladek's device would have provided the function of "air generated impact" and pulverization of the pharmaceutical composition because Sladek also teaches a housing large enough to provide a pulverization surface (see fig.2A) for the pharmaceutical to be impacted when the outside air is introduced into the housing by the inlet flow path, auxiliary flow path, and/or suction port prior to inhalation.

As to claim 2, the scope of claim 2 is substantially overlapping with clam 1. Therefore, Sladek teaches the invention specified in claim 2 as applied for claim 1. Sladek further teaches a mouthpiece (11) provided at one end of the housing, the mouthpiece being provided with a mouth-side flow path (11D) which communicates with the inhalation flow path and a divider (12A) having an orifice (17) at least one of the mouth-side flow path or the inhalation flow path for reducing the diameter of the flow path by forming a step part (12).

As to claim 3, Sladek teaches the inhalation device for transpulmonary administration according to Claim 2, wherein a plurality of dividers (multiple dividers (16) are depicted in fig.6) each having an orifice (plurality of 17 depicted in fig.6) is provided at appropriately spaced intervals.

As to claim 4, Sladek teaches the inhalation device for transpulmonary administration according to Claim 2 or 3 having a mouthpiece (11) that includes an auxiliary flow path (20A) for directly inhaling the outside air which does not communicate with the inhalation flow path and the mouth-side flow path. Sladek further teaches wherein the inhalation device for transpulmonary administration is configured such that the pulverized pharmaceutical composition is introduced to the inhalation flow path and the mouth-side flow path, and at the same time the outside air is directly introduced to the auxiliary flow path by the inhalation-induced pressure as applied for claim 1.

As to claim 5, the scope of claim 5 is substantially overlapping with clam 1. Therefore, Sladek teaches the invention specified in claim 5 as applied for claim 1. Sladek further teaches the inhaled outside air to flow into the mouth-side flow path though an air outlet which opens into the mouth side flow path (see outlet though the mouthpiece 11 in fig.2A). Sladek continues to teach wherein the inhalation device for transpulmonary administration is configured such that the air outlet allows the outside air to flow in the air discharge direction of the mouth-side path and is formed in a ring shaped along the inner circumferential wall surface of the mouth-side flow path (see a ring shaped outlet though 11D in fig.6).

As to claim 6, Sladek teaches the inhalation device for transpulmonary administration according to Claim 5; wherein the inhalation device for transpulmonary administration is

configured such that a divider (12A) having an orifice (17) for reducing the diameter of the flow path is formed at the mouth-side flow path; and outside air containing the pulverized pharmaceutical composition passes through the orifice, and thereafter is surrounded by outside air flowing into the mouth-side flow path from the ring-shaped air outlet (see figs. 2A, 2B, and 6).

As to claim 7, Sladek teaches the inhalation device for transpulmonary administration according to Claim 6; wherein a flow-path length of the orifice is formed to be elongated to the air discharge direction of the mouth-side flow path (see fig.2B).

Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sladek US 6,039,042 as applied to claim 1 above, and further in view of Yamashita et al. US 2003/0101995A1.

As to claim 8, Sladek lacks the chamber for containing a non-powder cake-like form which disperses in air by an air-generated impact and accommodating a vessel sealed by a sealing member, and an unsealing member for releasing the sealed condition provided by the sealing member, wherein the inhalation device for transpulmonary administration is configured such that the vessel is unsealed by the unsealing member to establish communication between the chamber and the inside of the vessel, and the air-generated impact is applied by the inhalation-induced pressure to the pharmaceutical composition contained in the vessel. However, Yamashita teaches a vessel and pharmaceutical discharge mechanism of a dry powder inhaler where the vessel houses a freeze-dried ("cake like form") composition in a non-powder form, have a needle part with a discharge flow path, a stopper that seals up the vessel which is pierced by the needle parts in order to communicate an air jet flow path and a discharge flow path with

the inside of the vessel. Yamashita further teaches such vessel structure allows for air to be jetted into the vessel from the air jet flow path in order to break down the freeze dried composition into fine particles by the impact of the jetted air (see page 5, paragraphs 94-96). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the vessel of Sladek in order to incorporate a vessel that can administer inhalation of a freeze-dried pharmaceutical composition, and further provide the vessel with sealed and unsealed members in order to create jetted air into the vessel to break down the freeze-dried composition into fine particles by the impact of the jetted air as taught by Yamashita.

As to claim 9, Sladek lacks a check valve to prevent the pulverized pharmaceutical composition from flowing to the outside from the air inlet flow path. However, Yamashita teaches a check valve (see fig.5, 30 of Yamashita) to control the pressure inside a vessel (see page 23, paragraph 430 of Yamashita). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the canister/vessel of Sladek with a check valve in order to control the pressure inside the canister/vessel as taught by Yamashita.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the **suction port (claim 1), step part**

(claim 2), and plurality of dividers (claim 3) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities: Applicant is requested to review reference number cited for the inhalation flow path (1) and mouth-side flow path (11). While reviewing the application, the Examiner came across recitations where both flow paths were indicated as reference number 11 (see specification page 15, line 6). Applicant is requested to review the entire disclosure and make appropriate corrections.

Claim Objections

Claim 4 is objected to because of the following informalities: should "a mouthpiece" in line 2 be "said mouthpiece"? Appropriate correction is required.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Mecikalski (US 5,577,497), Johnson (US 5,654,007), Ivri (US 5,758,637), Smith (US 5,785,049), Jaeger (US 5,964,416), Kriesel (US 5,993,421), Haber (US 5,435,282), and Drachmann (US 6,712,070B2) are cited to teach inhalation device.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shumaya B. Ali whose telephone number is 571-272-6088. The examiner can normally be reached on M-W-F 8:30am-5:00 pm.

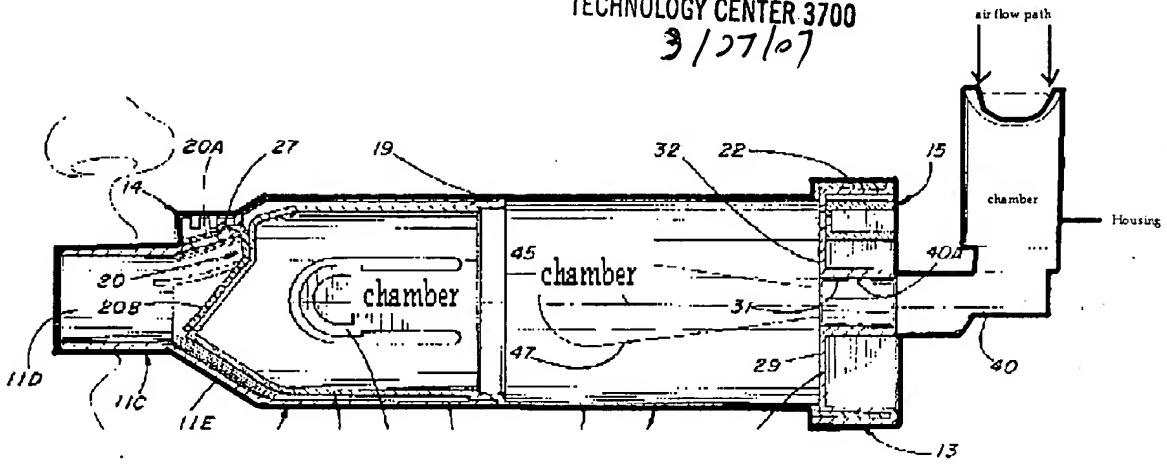
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

3/25/07

Shumaya B. Ali
Examiner
Art Unit 3771

JUSTINE R. YU
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700
3/27/07



Prior Art
Fig.2A
US 6,039,042